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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/900,801	07/06/2001	Richard Eustis Fulton III	ARTM 1000-SUS	6827

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EXAMINER

SZMAL, BRIAN SCOTT

ART UNIT	PAPER NUMBER
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3736

DATE MAILED: 04/18/2003

14

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/900,801

Applicant(s)

FULTON ET AL.

Examiner

Brian Szmal

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 February 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 89,90,92-103,118-139,141-148 and 150-160 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 89,90,92-94,97-103,118-139,141-148,150-156 and 160 is/are rejected.
- 7) ☒ Claim(s) 95,96 and 157-159 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

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Terminal Disclaimer

1. The Applicant states a Terminal Disclaimer was attached to the Amendment and Remarks Filed on February 25, 2003, but no Terminal Disclaimer was filed.

Double Patenting

2. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

3. Claim 89 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1 and 19 of U.S. Patent No. 6,270,464 B1. Although the conflicting claims are not identical, they are not patentably distinct from each other because the issued claims are written in a broader language than the current claim.

4. Claim 93 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 11 of U.S. Patent No. 6,270,464 B1. Although the conflicting claims are not identical, they are not patentably distinct from

each other because the issued claim is written in a broader language than the current claim.

5. Claim 90 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 10 of U.S. Patent No. 6,270,464 B1. Although the conflicting claims are not identical, they are not patentably distinct from each other because the issued claim is written in a broader language than the current claim.

6. Claims 94, 97-100, 102 and 103 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 12, 13, 19, 22, 21, 3 and 6 of U.S. Patent No. 6,270,464 B1. Although the conflicting claims are not identical, they are not patentably distinct from each other because the issued claims are written in a broader language than the current claims.

8. Claim 92 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 11 and 19 of U.S. Patent No. 6,270,464 B1. Although the conflicting claims are not identical, they are not patentably distinct from each other because the issued claims are written in a broader language than the current claim.

9. Claims 118, 127 and 136 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 26, 30 and 40 of U.S. Patent No. 6,270,464 B1. Although the conflicting claims are not identical, they are not patentably distinct from each other because the issued claims are written in a broader language than the current claims.

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10. Claims 119-124, 128-133, 137-139, 141 and 142 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 27, 29, 31, 39, 42 and 43 of U.S. Patent No. 6,270,464 B1. Although the conflicting claims are not identical, they are not patentably distinct from each other because the issued claims are written in a broader language than the current claims.

11. Claims 126, 135, 146, 148, 152 and 160 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 26 of U.S. Patent No. 6,270,464 B1. Although the conflicting claims are not identical, they are not patentably distinct from each other because the issued claim is written in a broader language than the current claims.

12. Claim 125 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 25 of U.S. Patent No. 6,270,464 B1. Although the conflicting claims are not identical, they are not patentably distinct from each other because the issued claim is written in a broader language than the used claim.

13. Claims 134 and 143 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 32 of U.S. Patent No. 6,270,464 B1. Although the conflicting claims are not identical, they are not patentably distinct from each other because the issued claim is written in a broader language than the current claim.

14. Claims 144 and 145 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 26 and 27 of U.S.

Patent No. 6,270,464 B1. Although the conflicting claims are not identical, they are not patentably distinct from each other because the issued claims are written in a broader language than the current claims.

15. Claims 147 and 154 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 31 of U.S. Patent No. 6,270,464 B1. Although the conflicting claims are not identical, they are not patentably distinct from each other because the issued claim is written in a broader language than the current claim.

16. Claim 150 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 40 of U.S. Patent No. 6,270,464 B1. Although the conflicting claims are not identical, they are not patentably distinct from each other because the issued claim is written in a broader language than the current claim.

Claim Objections

17. Claim 93 is objected to because of the following informalities: The end of the claim is written as "site,." It should be changed to "site.". Appropriate correction is required.

Claim Rejections - 35 USC § 102 & 103

18. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in-

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- (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effect under this subsection of a national application published under section 122(b) only if the international application designating the United States was published under Article 21(2)(a) of such treaty in the English language; or
- (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that a patent shall not be deemed filed in the United States for the purposes of this subsection based on the filing of an international application filed under the treaty defined in section 351(a).

19. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

- (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

20. Claims 89, 90 and 101-103 are rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Mavity et al ('057).

Mavity et al disclose a bioabsorbable brachytherapy and chemotherapy delivery device and method and further disclose a bioabsorbable element in a pre-delivery state; the element comprises a chemotherapeutic agent; the element is in a post-delivery state at the target tissue site; the element is softer in the post-delivery state; and the element is physically different in the post-delivery state than in the pre-delivery state. See Column 4, lines 20-56; Column 5, lines 29-65; Column 6, lines 27-39; Column 8, lines 34-50; Column 9, lines 48-60; Column 10, lines 23-28; and Column 12, lines 12-14 and 51-59. Even though Mavity et al does not explicitly disclose the use of remote visualization to visualize the implanted element, it is disclosed in Mavity et al, that the element will degrade to such an extent over time that the element does not interfere with the imaging of the local tissue. Therefore it would have been obvious to one of ordinary skill in the art to realize the element of Mavity et al is in fact visualizable before the element has

been fully absorbed, because the element does interfere with the imaging of the local tissue.

21. Claims 92 and 93 are rejected under 35 U.S.C. 102(e) as being anticipated by Mavity et al ('057).

Mavity et al, as discussed above, disclose a bioabsorbable brachytherapy and chemotherapy delivery device and method and further disclose a bioabsorbable element in a pre-delivery state; the element comprises a chemotherapeutic agent; the element is in a post-delivery state at the target tissue site; the therapeutic agent comprises a radiation agent; the element is softer in the post-delivery state; and the element is physically different in the post-delivery state than in the pre-delivery state.

See Column 4, lines 20-56; Column 5, lines 29-65; Column 6, lines 27-39; Column 8, lines 34-50; Column 9, lines 48-60; Column 10, lines 23-28; and Column 12, lines 12-14 and 51-59.

22. Claims 144, 146-148, 150-156 and 160 are rejected under 35 U.S.C. 103(a) as being unpatentable over Haaga in view of Mavity et al.

Haaga discloses a biopsy system and method and further discloses taking a tissue sample; positioning a bioabsorbable element at the target site at the time of taking the tissue sample; and the tissue taking step is carried out at a biopsy site. See Column 3, lines 16-54; Column 4, lines 3-19 and 25-32; Column 7, lines 20-67; and Column 8, lines 1-9.

Haaga however fails to disclose a remotely visualizable bioabsorbable element; positioning the remotely visualizable element at the target site; medically treating the

target site; delivering a therapeutic agent to the site; the therapeutic agent is a chemotherapy agent, gene therapy, or ionizing energy.

Mavity et al, as discussed above, disclose a bioabsorbable brachytherapy and chemotherapy delivery device and method and further disclose a remotely visualizable bioabsorbable element; positioning the remotely visualizable element at the target site; medically treating the target site; delivering a therapeutic agent to the site; the therapeutic agent is a chemotherapy agent, gene therapy, or ionizing energy. See Column 4, lines 20-56; Column 5, lines 29-65; Column 6, lines 27-39; Column 8, lines 34-50; Column 9, lines 48-60; Column 10, lines 23-28; and Column 12, lines 12-14 and 51-59.

Since both Haaga and Mavity et al disclose means for positioning a bioabsorbable element at a target site within tissue for therapy, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the method of Haaga to include a remotely visualizable bioabsorbable element further comprising a therapeutic agent, as per the teachings of Mavity et al, since it would provide a localized therapy to surrounding tissue to prevent the possible spread of cancerous tissue. Even though Mavity et al does not explicitly disclose the use of remote visualization to visualize the implanted element, it is disclosed in Mavity et al, that the element will degrade to such an extent over time that the element does not interfere with the imaging of the local tissue. Therefore it would have been obvious to one of ordinary skill in the art to realize the element of Mavity et al is in fact visualizable before the element has been fully absorbed, because the element does interfere with the imaging of the local

tissue. It also would have been obvious to use remote imaging techniques to assist in the placement of element since it is well known in the art to utilize imaging techniques such as ultrasound, MRI and other radiographic techniques to accurately position the element at the target site. It also would have been obvious to one of ordinary skill in the art to relocate the biopsy site by finding the element, since the element is placed at the target site once the biopsy is performed. It is also well known in the art to perform biopsies at target sites, test the tissue and then apply therapies, including radiation and chemotherapy following further removal of tissue, if the biopsy sample has proven to be malignant. It is also obvious to one of ordinary skill in the art to relocate the target site prior to treating the site, since it is well known in the art to find or relocate the tumor site prior to the application of radiation or chemotherapy.

Allowable Subject Matter

23. The following is a statement of reasons for the indication of allowable subject matter: Claims 94-97, 118-139 and 141-143 are allowable over the prior art since no prior art could be found concerning or suggesting a bioabsorbable element that is capable of yielding therapy via delivery of a therapeutic agent to or activating a therapeutic agent within the bioabsorbable element; and the bioabsorbable element comprising means for subsequently receiving a therapeutic agent. These claims will be allowable once a Terminal Disclaimer has been filed in response to the Double Patenting rejection set forth above.

24. Claims 95, 96, 98-100, 145 and 157-159 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.


Claims 95 and 96 are claims that are not rejected under the Double Patenting rejection above. Claims 98-100 and 145 are claims that are rejected under the Double Patenting rejection above, but contain allowable subject matter over the prior art.


Response to Arguments

25. Applicant's arguments with respect to claims 89, 90, 92, 93, 101-103, 144-156 and 160 have been considered but are moot in view of the new ground(s) of rejection.

26. Applicant's arguments, see Paper No. 13, filed February 25, 2003, with respect to Claims 94-97, 118-139 and 141-143 have been fully considered and are persuasive. The rejections of Haaga, Mavity et al, and Sirimanne et al have been withdrawn.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian Szmaj who's telephone number is (703) 308-3737 and group fax number is (703) 308-0758. The examiner can normally be reached on Monday-Friday, with second Fridays off.

BS 
April 16, 2003


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